

[0057] As depicted in FIG. 5, the treatment of a clean polyester substrate surface with MESNA did not significantly alter the hydrophilicity of the clean polyester substrate as evidenced by water contact angle. The difference in the measured water contact angles B and D was the within 5%. However, the data of FIG. 5 indicates that the treatment of a clean gold substrate surface with MESNA significantly alters (i.e., enhances) the hydrophilicity of the surface as evidenced by water contact angle. The clean gold substrate surface had a water contact angle of approximately 78 degrees, following treatment with MESNA, the water contact angle was approximately 52 degrees. It is postulated, without being bound, that such a reduction in water contact angle, and therefore increase in hydrophilicity, improves the uniformity and adhesion of enzymatic reagent layers to such treated gold surface. In other words, the treated gold substrate surface, which has hydrophilicity-enhancing moieties thereon, will exhibit improved uniformity and adherence with respect to enzymatic reagent layers. In addition, the data of FIG. 6 indicate that the reduction in water contact angle persists after two weeks of storage. Such persistence in enhanced hydrophilicity is beneficial with respect to easing manufacturing time constraints.

[0058] Table 1 below lists the water contact angle of gold substrate surfaces that had received various treatments. For treatments 1-15 of Table 1, cleaned gold substrates were exposed to MESNA solutions as indicated in the Table. Treatment 16 consisted of cleaning a gold substrate surface but no exposure to MESNA and treatment 17 involved no cleaning or exposure to MESNA. The data of Table 1 indicate that a significant reduction in water contact angle and, thus, enhancement in hydrophilicity and enzymatic reagent layer adhesion and uniformity, can be achieved with an exposure to MESNA for a time period as short as 1 minute. The data of Table 1, therefore, indicate that the manufacturing of metal electrodes with hydrophilicity-enhancing moieties on their upper surfaces could be accomplished using continuous web-based processes (such as the processes described in WO 01/73109, which is hereby incorporated in full by reference) that have been modified to include a metal electrode upper surface treatment module.

TABLE 1

Treatment #	MESNA Concentration (g/L)	Time (min)	Average Water Contact Angle (degrees)
1	16	1	41
2	16	2	52
3	16	5	49
4	16	10	50
5	16	15	52
6	4	1	48
7	4	2	65
8	4	5	53
9	4	10	63
10	4	15	55
11	1	1	60
12	1	2	54
13	1	5	69
14	1	10	64
15	1	15	58
16	Cleaned	—	78
17	Not cleaned	—	79

COMPARATIVE EXAMPLE

[0059] To demonstrate characteristics and benefits of electrochemical-based analytical test strips according to embodiments of the present invention, a comparison between an electrochemical-based analytical test strip with gold electrodes in the absence of hydrophilicity-enhancing moieties (i.e., a comparison electrochemical-based analytical test strip) and an electrochemical-based analytical test strip with gold metal electrodes according to an exemplary embodiment of the present invention was undertaken.

[0060] FIG. 7 is an artist's rendition of a photographic image of a portion 100 of an electrochemical-based analytical test strip with gold electrodes in the absence of hydrophilicity enhancing moieties on the upper surface of the gold electrodes. FIG. 7 depicts portion 100 prior to the application of a blood sample thereto. Portion 100 includes an electrically-insulating substrate 102, an insulation layer 104, counter electrode exposed portion 106, first working electrode exposed portion 108, second working electrode exposed portion 110 and enzymatic reagent layer 112. The composition of enzymatic reagent layer 112 and the method by which it was applied are described in U.S. Pat. No. 5,708,247, which is hereby fully incorporated by reference.

[0061] As is evident from FIG. 7, enzymatic reagent layer 112 exhibits significant non-uniformity over counter electrode exposed portion 106, first working electrode exposed portion 108, and second working electrode exposed portion 110, thus indicating a lack of adherence thereto. Such a lack of uniformity and/or adherence is postulated to be a contributor to unreliable and inaccurate electrochemical-based analytical test strip results. In addition, it has been determined that enzymatic reagent layers disposed on an electrode surface in the absence of hydrophilicity-enhancing moieties are easily damaged during physical manipulation that occurs in conventional test strip manufacturing processes and can separate from the electrode surface upon exposure to a fluid sample.

[0062] FIG. 8 is a chart of current response versus YSI determined glucose concentration for a comparison electrochemical-based analytical test strip with gold metal electrodes in the absence of hydrophilicity-enhancing moieties on the upper surface of the gold electrodes (i.e., comparison electrochemical-based analytical test strips corresponding effectively to the depiction of FIG. 7). The best fit line and R^2 value for the data of FIG. 8 are indicated on the chart. The data and R^2 value of FIG. 8 are an indication of the repeatability and accuracy of measurements made with the comparison electrochemical-based analytical test strips with gold electrodes.

[0063] As noted above with respect to FIG. 7, enzymatic reagent layer 112 exhibited a lack of uniformity and adherence when employed with a gold metal electrode. It is postulated that such a lack of uniformity and adherence will lead to inaccuracies and lack of measurement repeatability as it adversely and unpredictably affects the sensing area of the working electrodes.

[0064] FIG. 9 is an artist's rendition of a photographic image of a portion 200 of an electrochemical-based analytical test strip hydrophilicity-enhancing moieties disposed on the upper surface of gold electrodes. FIG. 9 depicts portion 200 prior to the application of a blood sample thereto.